THE HONORABLE JOHN C. COUGHENOUR

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

PAMELA C. SHELP and SCOTT R. SHELP, Plaintiffs, v. ALLERGAN, INC., *et al.* Defendants.	CASE NO. C18-1427-JCC ORDER

This matter comes before the Court on Defendants Allergan, Inc., Allergan USA, Inc., Allergan Sales, LLC, and Allergan PLC's (collectively "Allergan") motion to dismiss (Dkt. No. 12). Having thoroughly considered the parties' briefing and the relevant record, the Court finds oral argument unnecessary and hereby GRANTS the motion for the reasons explained herein.

I. BACKGROUND

In 2011, Plaintiff Pamela Shelp underwent breast augmentation surgery. (Dkt. No. 1-1 at 6.) Ms. Shelp alleges that within a few months or her surgery, she developed several physical, muscular, and neurological symptoms caused by the breast implants. (*Id.* at 7.) In 2017, Ms. Shelp had surgery to remove the implants. (*Id.*) The doctor who performed that surgery found that scar tissue around the implants had tightened, causing the right implant to rupture. (*Id.*) The doctor determined that Allergan manufactured the left implant, but was unable to conclusively

identify the right implant's manufacturer.[1]

On June 1, 2018, Ms. Shelp and her husband filed a lawsuit in King County Superior Court against Allergan and several other Defendants. (*Id.* at 1.) The Shelps allege that Allergan's breast implants were negligently designed, and that Allergan knew or should have known of their "hazards and dangerous propensities," but failed to warn Ms. Shelp of those risks. (*Id.* at 9.) The Shelps allege causes of action for negligence, as well as violations of Washington State's products liability statute and Consumer Protection Act (CPA). (*Id.* at 10.)

On September 27, 2018, Allergan removed the case to this Court and now moves to dismiss the claims against it. (Dkt. Nos. 1, 12.) Allergan argues that all of the Shelps' claims are expressly preempted by the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act of 1938. (Dkt. No. 12 at 2.) Allergan also asserts that the Shelps' complaint fails to plead sufficiently plausible factual allegations, and that their claims under Washington's CPA are improper.[2] (Dkt. No. 12 at 18–20.)

II. DISCUSSION

A. Legal Standard

A defendant may move to dismiss claims against it where the complaint "fail[s] to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). A complaint will survive a motion to dismiss if it contains factual allegations that, if true, state a plausible claim that the plaintiff is entitled to relief against the defendant. *Ashcroft v. Iqbal*, 556 U.S. 662, 677–78 (2009). When ruling on a motion to dismiss, the Court must accept as true all of the facts in the complaint, but will not draw unreasonable inferences from those facts or accept the validity of legal conclusions. *Vasquez v. Los Angeles ("LA") County*, 487 F.3d 1246, 1249 (9th Cir. 2007).

Generally, the Court must decide a motion to dismiss based solely on the facts set forth in

[1] Mentor Worldwide, LLC, another Defendant in this lawsuit, is the other alleged manufacturer of the right breast implant. (*See* Dkt. No. 1-1 at 7–8.)

[2] Because the Court finds that the Shelps' claims against Allergan are expressly preempted, it does not reach Allergan's other arguments.

the pleadings. *United States v. Corinthian Colls.*, 655 F.3d 984, 999 (9th Cir. 2011). However, the Court may take judicial notice of "matters of public record" not subject to reasonable dispute. Fed. R. Evid. 201. Thus, the Court may judicially notice the existence of a public record, as well as the record's content, so long as the content is not subject to reasonable dispute. *Lee v. City of Los Angeles*, 250 F.3d 668, 689–90 (9th Cir. 2001).

The Court takes judicial notice of the fact that the U.S. Food and Drug Administration (FDA) granted premarket approval to Allergan for the breast implants allegedly at issue in this case on November 17, 2006. (Dkt. No. 12 at 23–27.) Premarket approval refers to the process by which the FDA grants permission for manufacturers to market certain medical devices after a rigorous testing process meant to ensure that the device is reasonably safe for use. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315–20 (2008). The premarket approval for Allergan's Natrelle breast implants is documented in official, publicly available FDA records, the authenticity of which the Court finds is not subject to reasonable dispute.[3] *See Stengel v. Medtronic, Inc.*, 676 F.3d 1159, 1167 (9th Cir. 2012) (affirming district court's judicial notice of FDA's grant of premarket approval), *rev'd en banc on other grounds*, 704 F.3d 1224 (9th Cir. 2013).

B. Preemption under the MDA

The MDA expressly preempt state oversight of certain medical devices subject to FDA regulation. The relevant statute provides that:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable

[3] The FDA's letter granting premarket approval for Allergan's breast implants, as well as a summary of the implants' safety and effectiveness and FDA-approved labeling, is available on the FDA's website. *See U.S. Food & Drug Administration, Premarket Approval: Natrelle Silicone-Filled Breast Implants*, (Nov. 17, 2006), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020056.

to the device under this chapter.

21 U.S.C. § 360k(a).

The Supreme Court has set out a two-part test to determine if a state-law cause of action is preempted by the MDA. *Riegel*, 552 U.S. at 321–22. First, a court must determine if federal law imposes "requirement[s] applicable to the device" at issue. *Id.* at 322. This showing is automatically satisfied where the FDA grants a device premarket approval. *Id.* If the first element is met, the court must determine if a plaintiff's claims seek to impose state requirements "different from, or in addition to" the relevant FDA requirements. *Id.* State common-law duties are "requirements" within the meaning of the MDA. *Id.* at 324. Thus, in *Riegel*, the Court held that state common-law claims—including negligent design and failure to warn—are preempted in cases involving medical devices that receive premarket approval. *Id.* at 321–30. The Court concluded that such claims are preempted because, if successful, they would impose state safety requirements that are different from the FDA's requirements pursuant to a premarket approval. *Id.* State-law claims that allege violations of FDA regulations, on the other hand, are not preempted. *Id.* at 330.

The Supreme Court's holding in *Riegel* applies to the Shelps' claims against Allergan. 552 U.S. 321–30. The FDA granted premarket approval for the Allergan breast implants allegedly at issue well before Ms. Shelp's breast augmentation surgery. (Dkt. No. 12 at 23–27.) Thus, federal law imposes requirements on those devices. *Riegel*, 552 U.S. at 322. The Shelps allege various products liability claims, including that the breast implants were negligently designed and manufactured, as well as that Allergan failed to warn Ms. Shelp about the risks associated with using them. (*See* Dkt. No. 1-1.) The legal theory underlying the Shelps' CPA claim is not clearly stated, but because CPA claims require "an unfair or deceptive act or practice," the Court concludes that the Shelps base their CPA cause of action on Allergan's failure to warn Ms. Shelp about the dangers of using its product. *Panag v. Farmers Ins. Co. of Wash.*, 204 P.3d 885, 889 (Wash. 2009). Nothing in the Shelps' complaint expresses or implies that the Allergan breast implant used by Ms. Shelp violated any FDA requirements. (*See*

generally Dkt. No. 1-1.) Thus, like the Plaintiffs in *Riegel*, the Shelps' claims seek to impose safety requirements on Allergan's breast implants that are both different from, and in addition to, the requirements imposed by the FDA's premarket approval. *See Riegel*, 552 U.S. 320–21. As a result, all of the Shelps' claims are expressly preempted by the MDA. 21 U.S.C. § 360k(a)(1).

III. CONCLUSION

For the foregoing reasons, the Allergan Defendants' motion to dismiss (Dkt. No. 12) is GRANTED. All of Plaintiffs' claims against Defendants Allergan, Inc., Allergan USA, Inc., Allergan Sales, LLC, and Allergan PLC are DISMISSED with prejudice.

DATED this 2nd day of November 2018.

John C. Coughenour
UNITED STATES DISTRICT JUDGE